K083647

# SPECIAL 510(K) PREMARKET SUMMARY

## Valo™

JAN 23 2009

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for Valo™

### Applicant's Name and Address

Ultradent Products, Inc
505 West 10200 South
South Jordan, UT 84095

| | |
|---|---|
| Contact Person | Diane Rogers |
| Title | Regulatory Affairs Manager |
| Telephone | 800-552-5512 x4491, 801-553-4491 |
| FAX | 801-553-4609 |
| Date Summary Prepared | December 11, 2008 |


### Name of the Device

| | |
|---|---|
| Trade Name | Valo™ |
| Common Name | Activator, ultraviolet for polymerization |
| Device Classification | II |
| Classification Product Code | EBZ |

### Legally Marketed Predicate Device to Which Equivalence is Claimed

The predicate device is Palmlight (K003383) This device is manufactured and distributed by Ultradent Products, Inc , 505 West, 10200 South, South Jordan, Utah 84095

**Product Description** Valo™ is an activator, ultraviolet for polymerization In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials

**Indications for Use:** Source of illumination for curing photo-activated dental restorative materials and adhesives

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

JAN 2 3 2009

Re K083647
Trade/Device Name Valo™
Regulation Number 21 CFR 872 6070
Regulation Name Ultraviolet Activator for Polymerization
Regulatory Class II
Product Code EBZ
Dated January 14, 2009
Received January 14, 2009

Dear Ms Rogers

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Ginette Y Michaud, M D
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Statement of Indications for Use

510(k) Number (if known) K083647

Device Name Valo™

Indications for Use

**Source of illumination for curing photo-activated dental restorative materials and adhesives.**

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083647



*(Posted November 13, 2003)*